K050703

APR 2 1 2005

12. SUMMARY OF SAFETY AND EFFECTIVENESS

Submission in accordance with the requirements of 21 CFR Part 807.87(h)

- **Submitter** : Medis medical imaging systems b.v.
  Address : Schuttersveld 9
  : 2316 XG Leiden, The Netherlands
  Telephone : +31 71 522 3244
  Fax : +31 71 521 5617
  Contact Person : J.I. Hollander, Quality Coordinator
  Prepared : March 03, 2005

- **Device Name** : Automatic quantitative analysis of MR brain images
  Common Name : QBrain
  Device Class. Name : Class II; PACS software
  Regulation Number : 21 CFR 892.2050 (90 LLZ)

- **Predicate Device(s)** : IQuantify workstation software, **K011196**

- **Device Description and indications for Use**

QBrain is able to read DICOM MR images from all major MRI vendors. Mask data, generated by automatic segmentation and/or manual editing, and quantitative results can be saved in separate files enabling the comparison of results from different users and easy export to standard spreadsheet software.
Neuro-(radio)logists in hospitals and specialists in core labs use the QBrain standalone analytical software package in image post-processing. The provided objective and quantitative values support the diagnostic decision process or are used in the evaluation of follow-up studies about disease evolution and / or therapy response.

- **Intended use**

The QBrain software has been developed for the objective and reproducible analysis of MR images of the brain. It performs quantitative analyses on MR brain images based on automatic segmentation. More specifically, it quantifies the volumes of intracranial cavities, areas that contain cerebrospinal fluid (CSF), and white matter hyperintensities (lesions).
These parameters should only be used by trained medical professionals. They may be used to support diagnosis in clinical practice and to reach conclusions in clinical trials.

- **Substantial equivalence Information**

QBRAIN is substantially equivalent to the Predicate Device of Insightful Corporation (IQantify, K011196) using the same technological technique for the same intended use.

Conclusion

It is our opinion, QBrain is safe because during the development potential hazards were controlled by a risk management plan, including hazard and risk analyses, verification and validation tests. Evaluations by hospitals and literature support this statement. The software package QBrain itself will not have any adverse effects on health. The operator interprets the objective values of the analysis and chooses to accept or reject the results.
In current thinking, the level of concern for the standalone software in image post-processing is 'Minor' and the use of QBrain does not change the intended use of MRI scanners in practice, nor does the use result in any new potential hazard.
Based of the information supplied in this 510(k), we conclude that the subject device is safe, effective and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1 2005

Mr. J.I. Hollander
Quality Coordinator
Medis Medical Imaging Systems bv
Schuttersveld 9, 2316 XG Leiden
THE NETHERLANDS

Re: K050703
Trade/Device Name: QBrain
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: LLZ
Dated: March 3, 2005
Received: March 18, 2005

Dear Mr. Hollander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050703

Device Name: QBrain

Indications For Use: The QBrain software has been developed for the objective and reproducible analysis of MR images of the brain. It performs quantitative analysis of MR brain images based on automatic segmentation. More specifically, it quantifies the volumes of intracranial cavities, areas that contain cerebrospinal fluid (CSF), and white matter hyperintensities (lesions).
These parameters should only be used by trained medical professionals. They may be used to support diagnosis in clinical practice and to reach conclusions in clinical trials.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050703